

HEALTH CARE REGULATORY MODERNIZATION INITIATIVE

Background Paper: New Model for Article 28 Sites Performing Outpatient Procedures

Problem Statement:

Diagnostic and therapeutic procedures, including surgical procedures, that were once provided only in a hospital setting are increasingly being performed in the outpatient setting. This has resulted in an interest among providers to perform less invasive diagnostic, therapeutic and/or surgical procedures, historically only allowed in hospitals and Ambulatory Surgery Centers (ASCs), in less restrictive outpatient settings. However, a myriad of factors must be considered in determining the appropriate outpatient setting for such procedures, including, but not limited to, patient-specific factors, invasiveness and complexity of the procedure(s), level of sedation/anesthesia, and physical plant standards.

Background:

Increasingly, health care services that were once provided only in an inpatient hospital setting are being performed in the outpatient setting. This is due to the development of new less invasive procedures, new technologies and techniques rendering these procedures to be safer, patient and/or physician preferences for alternatives to inpatient hospital care, and the desire to provide high quality care in the most cost-effective setting. Article 28 outpatient settings in which procedures can be performed include Diagnostic and Treatment Centers (DTCs), DTC extension clinics, and hospital outpatient departments including hospital extension clinics and DTC's with Ambulatory Surgery Center designation. PHL Section 230-A also allows certain types of procedures to be performed in Office Based Surgery (OBS) Settings, these private practices are not licensed but must be accredited.

The Department has two levels of Article 28 outpatient clinic service categories:

Article 28 DTC: Primary Care and/or Other Medical Specialties: Providers are limited to performing non-invasive procedures involving local or peripheral regional anesthesia and/or minimal sedation which may be performed in an exam room. DOH surveys non-accredited free standing DTCs at a 5-year survey interval.

Article 28 DTC with ASC designation: Ambulatory Surgery: Providers may perform non-invasive, minimally invasive and/or invasive procedures and/or administer moderate and deep sedation, spinal and general anesthesia in an operating room or class 3 Imaging room. DOH surveys a sample selected by CMS of deemed ASCs and 25% of non-deemed ASCs per year (resulting in a 4-year survey interval).

Currently all clinics performing invasive or surgical procedures or providing greater than minimal sedation are required to be licensed as a DTC with an Ambulatory Surgery service designation and be federally certified as an Ambulatory Surgery Center (ASC).

Steps Taken:

A DOH workgroup was formed to evaluate whether there were certain types of procedures that could be performed safely in an outpatient clinic versus an ASC. The workgroup took the following approach:

- Reviewed related CON applications;
- Assessed the nature of the outpatient procedure being proposed;
- Examined the literature and current regulatory requirements of the different settings;

The workgroup is proposing to allow outpatient clinic settings, including DTCs, DTC extension clinics, and hospital extension clinics, to perform certain procedures subject to specific requirements for patient selection, physical plant, staffing, level of sedation/anesthesia, and patient monitoring.

Possible Solutions to Discuss:

The Department is proposing to add another DTC service category:

Article 28 DTC with OP Certification: Outpatient Procedures: Providers may perform non-invasive and/or minimally invasive procedures and/or administer up to moderate sedation and/or epidural anesthesia in a procedure room or class 2 Imaging room.

DTCs seeking to be certified in the Outpatient Procedure category would be required to be accredited and have a State survey at a more frequent 3-year interval.